

Wyeth

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April 5, 2004

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2004D-0041 – Draft Guidance for Industry on
Providing Regulatory Submissions in Electronic Format—
Content of Labeling

Dear Sir/Madam:

Wyeth is submitting written comments on the draft guidance for industry entitled, “Providing Regulatory Submissions in Electronic Format--Content of Labeling; 69 FR 5552; February 5, 2004

Wyeth is one of the world’s largest research-based pharmaceutical and health care companies. It is a leader in the discovery, development, manufacturing, and marketing of prescription drugs and over-the-counter medication, with leading products in women’s health care, cardiovascular, central nervous system, anti-inflammatory, infectious disease, hemophilia, and oncology categories, and is also a major manufacturer of preventative vaccines.

In general, Wyeth supports the concept of providing the content of labeling for marketing applications in electronic format. Wyeth is an active member of the PhRMA Electronic Regulatory Submissions Working Group that was formed to study the Structured Product Labeling (SPL) specification, and to help test its implementation with the FDA. We are concerned, however, that FDA is allotting insufficient time for development and testing prior to transition to the SPL standard proposed in the referenced draft guidance. The amount of time needed for this transition would be dependent on the finalization of the standard, development of tools, and availability of vendor tools and pilot results. In addition, Wyeth is concerned with the divergence of standards between the ICH countries, specifically the Product Information Management initiative in Europe and the FDA SPL initiative. It is likely that each proposed process will result in different specifications and thus more complex labeling text management systems.

Finally, Wyeth fully supports the comments that have been submitted by both PhRMA and the Biotechnology Industry Organization (BIO) concerning the above-referenced draft guidance.

Wyeth

We are submitting the enclosed comments in duplicate. Wyeth appreciates the opportunity to comment on the above-mentioned draft guidance for industry.

Sincerely,

A handwritten signature in black ink, reading "Roy J. Baranello, Jr." with a stylized flourish at the end.

Roy J. Baranello, Jr.
Assistant Vice President,
Worldwide Regulatory Affairs